

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE BENDAMUSTINE CONSOLIDATED
CASES

C.A. No. 13-2046-GMS (consolidated)

**DEFENDANTS SAGENT, DRL, UMAN AND INNOPHARMA'S
RULE 12(c) MOTION FOR JUDGMENT ON THE PLEADINGS WITH RESPECT TO
PLAINTIFF'S CLAIMS FOR INFRINGEMENT OF THE '190 AND '863 PATENTS**

Defendant Sagent Pharmaceuticals, Inc. ("Sagent"), together with defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. ("DRL"), Uman Pharma, Inc. ("Uman"), and InnoPharma, Inc. ("InnoPharma") respectfully move for judgment on the pleadings under Fed. R. Civ. P. 12(c) with respect to plaintiff's claims for infringement of United States Patent Nos. 8,436,190 ("the '190 patent") and 8,609,863 ("the '863 patent").¹ Defendants are well aware of this Court's reluctance in entertaining dispositive motions to resolve patent litigation, but Cephalon cannot sustain its claims for infringement of the '190 and '863 patents.

First, defendants' ANDA products cannot literally infringe the '190 and '863 patents. The '190 and '863 patents claim compositions comprising, among other things, tertiary-butyl alcohol. Defendants' ANDA products do *not* contain tertiary-butyl alcohol, a required element of each of the patent claims.

¹ Defendant Uman has not been sued on the '863 patent.

Second, Cephalon cannot rely on the doctrine of equivalents to prove infringement. The '190 and '863 patents disclose, but do not claim, specific alternative solvents to tertiary-butyl alcohol. Under established Federal Circuit precedent, the disclosure-dedication rule bars Cephalon's claims for infringement under the doctrine of equivalents.

Thus, this is one of those cases where judgment on the pleadings is entirely appropriate.² There is no literal infringement, and as a matter of law, Cephalon is estopped by the disclosure-dedication rule from claiming infringement under the doctrine of equivalents.

ARGUMENT

"Judgment on the pleadings should only be granted if it is clearly established that no material issue of fact remains to be resolved and that the movant is entitled to judgment as a matter of law." *Rodriguez v. Stevenson*, 243 F. Supp. 2d 58, 62 (D. Del. 2002) (Sleet, J.) (granting Rule 12(c) motion). A Rule 12(c) motion is especially useful where, as here, "only questions of law remain to be decided by the district court." 5C Charles A. Wright & Arthur R. Miller, *Federal Practice & Procedure*(s) 1367 (2004) (citing cases.)

In evaluating a motion for judgment on the pleadings, a court may consider the

² See e.g., *Genzyme Corp. v. Anchen Pharmaceuticals, Inc.*, Case No. 10-cv-00512-GMS (D. Del. October 31, 2011) (granting motion for judgment because the sole remaining issue before the Court was a question of law.) See also *Cumberland Pharma., Inc. v. InnoPharma, Inc.*, No. 12-618-LPS, 2103 WL 5945794 (D. Del. Nov. 1, 2013) (granting motion to dismiss claims for literal infringement and infringement under the doctrine of equivalents because defendant's ANDA product contained a chelating agent, while the asserted patent claimed compositions "free from a chelating agent"); *Cumberland Pharma., Inc. v. Sagent Agila LLC*, No. 12-825-LPS, 2013 WL 5913742 (D. Del. Nov. 1, 2013) (same).

pleadings, exhibits attached to the pleadings, matters of public record, and any documents “integral to or explicitly relied upon” in the pleadings. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997); *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993). Where the factual allegations in a complaint contradict a document attached to the pleadings, however, the document controls. *See ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 n.8 (3d Cir. 1994); *Sisk v. Sussex Cnty.*, Civ. No. 11-121-RGA, 2012 WL 1970879 (D. Del. June 1, 2012).

I. There is no dispute that defendants’ products do not literally infringe the ‘190 and ‘863 patents.

Claim 1 of the ‘190 patent is the only independent claim, and states the following:

“A pharmaceutical composition comprising bendamustine or bendamustine hydrochloride, mannitol, *tertiary-butyl alcohol* and water.” Ex. 1 (‘190 patent at claim 1).³

Likewise, the ‘863 patent’s independent claims cover compositions comprising bendamustine hydrochloride, mannitol, and *tertiary-butyl alcohol*. *See* Ex. 2 (‘863 patent at Claims 1 and 4).

Defendants’ ANDA products do *not* contain tertiary-butyl alcohol. The specific solvents that defendants use to prepare their final lyophilized compositions and the bendamustine hydrochloride drug substance in those compositions are listed in the chart attached as Exhibit 3. None of the organic solvents in defendants’ final lyophilized compositions, nor those involved in the manufacture of the active drug substance, is tertiary-butyl alcohol. Before Cephalon filed suit, defendants provided excerpts from their ANDA documents disclosing the specific solvents, or lack thereof,

³ Unless indicated otherwise, all emphasis is added.

in their ANDA products,⁴ and therefore, Cephalon knows that defendants' products do *not* comprise tertiary-butyl alcohol. In fact, Cephalon acknowledged reviewing defendants' ANDA documents in their complaints against defendants. *See* Cephalon's Complaint against Sagent (D.I. 1 at ¶ 43); Cephalon's Complaint against DRL (D.I. 1 at ¶ 32 ('190 patent, 13-2082-GMS)) and Cephalon's Second Complaint against DRL (D.I. 1 at ¶ 27 ('863 patent, 14-0334-GMS)); Cephalon's Amended Complaint against Uman (D.I. 24 at ¶ 31); and Cephalon's Complaints against InnoPharma (D.I. 469 at ¶ 22 ('863 patent, 14-590-GMS) and Answer to Third Affirmative Defense ¶ 4; D.I. 1 at ¶ 27 ('190 patent, 13-2081-GMS, and Answer)). Because defendants' ANDA products do not include each and every element of the independent claims of the '190 and '863 patents, there is no literal infringement as a matter of law. If an independent claim is not infringed, then it necessarily follows that the narrower claims that depend from the independent claim cannot be infringed. *See Wahpeton Canvas Co., Inc. v. Frontier, Inc.*, 870 F.2d 1546, 1553 n.9 (Fed. Cir. 1989).

II. The disclosure-dedication rule bars Cephalon's claims for infringement under the doctrine of equivalents because the '190 and '863 patents specifically disclose, but do not claim the solvents used in defendants' ANDA products.

Application of the disclosure-dedication rule is a question of law. *Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc.*, 429 F.3d 1364, 1378 (Fed. Cir. 2005).

It is well-established that "when a patent drafter discloses but declines to claim subject matter . . . [that] action dedicates that unclaimed subject matter to the public."

Johnson & Johnston Associates v. R.E. Service Co., Inc., et. al., 285 F.3d 1046, 1054 (Fed. Cir.

⁴ Defendant Uman also produced additional ANDA documents to Cephalon before Cephalon filed its Amended Complaint on October 9, 2014.

2002), citing *Maxwell v. J. Baker, Inc.*, 83 F.3d 1098, 1106 (Fed. Cir. 1996). “[A] patentee cannot narrowly claim an invention to avoid prosecution scrutiny by the PTO, and then, after patent issuance, use the doctrine of equivalents to establish infringement because the specification discloses equivalents.” *Id.* at 1055.

Defendants have done exactly what the patent laws and the Hatch-Waxman Act incentivize them to do—they have designed around the ‘190 and ‘863 patent claims, which do *not* recite any “solvent,” but instead have limitations directed only to tertiary-butyl alcohol. To rule otherwise—that “tertiary butyl alcohol” could cover any solvent—would “conflict with the primacy of the claims in defining the scope of the patentee’s exclusive rights.” *Id.* at 1054. But to fall within the disclosure-dedication rule, the disclosure must be sufficiently specific to permit a person of ordinary skill in the art to identify the unclaimed subject matter. *Pfizer, Inc.*, 285 F.3d at 1378-79 (quoting *PSC Computer Prods., Inc. v. Foxconn Int’l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir 2004)).

Here, the ‘190 and ‘863 patents, which share the same specifications, explain that,

In different aspects of this embodiment, the organic solvent is selected from one or more of tertiary butanol, n-propanol, n-butanol, isopropanol, ethanol, methanol, acetone, ethyl acetate, dimethyl carbonate, acetonitrile, dichloromethane, methyl ethyl ketone, methyl isobutyl ketone, 1-pentanol, methyl acetate, carbon tetrachloride, dimethyl sulfoxide, hexafluoroacetone, chlorobutanol, dimethyl sulfone, acetic acid, and cyclohexane.

Ex. 1, ‘190 patent at col. 5, ll. 6-14; Ex. 2, ‘863 patent at col. 5, ll. 5-12. For additional disclosures of these specific alternative solvents, *see also* Ex. 1, ‘190 patent at col. 16, ll. 39-50; Ex. 2, ‘863 patent, col. 16, ll. 34-46.

The disclosures in the '190 and '863 patent specifications are clear and explicit. The patentee identifies specific solvents that can be used as alternatives to tertiary-butyl alcohol, including those that defendants use to manufacture their ANDA products (*see* Ex. 3), but then only claimed the solvent tertiary-butyl alcohol. Accordingly, because of the disclosure-dedication rule, defendants' ANDA products cannot infringe the claims of the '190 and '863 patents under the doctrine of equivalents. *Johnson & Johnson Associates*, 285 F.3d at 1055 ("Having disclosed without claiming the steel substrates, Johnston cannot now invoke the doctrine of equivalents to extend its aluminum limitation to encompass steel."); *see also Aventis Pharms., Inc. v. Barr Labs., Inc.*, 335 F. Supp. 2d 558, 578 (D.N.J. 2004) (Where "[t]he plain language of the patent specification [] makes clear that the unclaimed excipients belong to the same class of therapeutically inert ingredients as those claimed, and moreover, that they can be used in the composition . . . [the patentee has] dedicated these ingredients to the public, and cannot now reclaim these excipients through application of the doctrine of equivalents.").⁵

For the foregoing reasons, the Court should grant defendants' motion for judgment on the pleadings of noninfringement under Counts III, IV, V and VI of the Complaint against Sagent; Counts III and IV of the first Complaint against DRL; Counts I and II of the second Complaint against DRL; Counts III and IV of the Amended

⁵ *See also Masimo Corp. v. Phillips Electronics N. Am. Corp.*, No. CA 09-080-LPS-MPT, 2013 WL 1332606, at *68 (D. Del. Apr. 2, 2013) (granting motion for summary judgment on the basis of the disclosure-dedication rule); *Juniper Networks, Inc. v. Palo Alto Networks, Inc.*, No. CA 11-1258-SLR, 2014 WL 527621, at *9 (D. Del. Feb. 6, 2014) (granting summary judgment because plaintiff was estopped from asserting the doctrine of equivalents, as a matter of law, because of amendments made by plaintiff during prosecution history that narrowed the scope of the claims).

Complaint against Uman; and Counts I and II of the '863 Complaint and Counts III and IV of the '190 Complaint against InnoPharma.

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CERTIFICATE OF SERVICE

I hereby certify that on December 5, 2014, I caused copies of the foregoing document to be served upon the following by ECF and in the manner indicated:

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